DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: Gynecare Intergel
Docket No. 02E-0150

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

FEB 21 2002

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,532,221, filed by Lifecore Medical, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Gynecare Intergel, the medical device claimed by the patent.

The total length of the regulatory review period for Gynecare Intergel is 2,438 days. Of this time, 1,453 days occurred during the testing phase and 985 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a clinical investigation on humans involving this device was begun: March 17, 1995.

   FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act for human tests to begin became effective on March 17, 1995.

2. The date the application was initially submitted with respect to the device under section 515 of the Federal Food, Drug, and Cosmetic Act: March 8, 1999.

   The applicant claims March 5, 1999, as the date the premarket approval application (PMA) for Gynecare Intergel] (PMA P990015) was initially submitted. However, FDA records indicate that PMA P990015 was submitted on March 8, 1999.

3. The date the application was approved: November 16, 2001.

   FDA has verified the applicant's claim that PMA P990015 was approved on November 16, 2001.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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